

**EXHIBIT “B”**

**DOCUMENT REQUESTS**

Please produce:

1. All documents relied upon by the deponent in preparing for this deposition.
2. The following documents for the design and development of Project Scion, TVT-PA and TVT+M, including but not limited to:
  - a. The Clinical Expert reports;
  - b. Each version of the Device Design Safety Assessment (DDSA's); Each version of the Design Failure Modes Effects Analysis (dFMEAs), Process Failure Modes Effects Analysis (pFMEAs), Application Failure Modes Effects Analysis (aFMEA);
  - c. Operating Procedures for Failure Modes and Effects Analysis;
  - d. Operating Procedure for Device Design Safety Assessment;
  - e. Design history files;
  - f. Design and specifications of equipment used in the production of Project Scion, TVT-PA and TVT+M;
  - g. Design and specifications of packaging used in the production of Project Scion, TVT-PA and TVT+M;
  - h. Specifications regarding sanitization and sterilization of Project Scion, TVT-PA and TVT+M, plant facilities and plant equipment;
  - i. Mesh Specifications;
  - j. Franchise procedure for medical device risk management plan;
  - k. Company procedure for medical device risk management plan;
  - l. Work Instruction for device risk management;
  - m. The Franchise procedure for the control and disposition of nonconforming product;
  - n. All company policies and procedures that apply to or relate to the Design History File;

- o. The Franchise Procedure for Corrective and Preventative Action (CAPA) as well as any other company policies and procedures related to CAPAs;
  - p. Risk management plans and reports for Project Scion, TVT-PA and TVT+M;
  - q. Members of product development team(s);
  - r. Operating procedures associated with a product development cycle;
  - s. Project Scion, TVT-PA and TVT+M quality manual;
  - t. Project Scion, TVT-PA and TVT+M quality plan;
  - u. Management responsibilities under a quality system;
  - v. Mesh product design review, design verification, process qualification and design transfer;
  - w. Mesh product device design requirements matrix;
  - x. Mesh product qualitative and quantitative characteristics worksheets, including but not omitted to hazard worksheet raking tables;
  - y. Mesh product validation test reports; and
  - z. Mesh product biocompatibility testing records;
3. Testing and validation of Project Scion, TVT-PA and TVT+M.